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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,854	03/30/2004	Fidel Realyvasquez	CSI-2024	5603

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EXAMINER
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STEWART, ALVIN J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/814,854

Applicant(s)

REALYVASQUEZ ET AL.

Examiner

Alvin J. Stewart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitations disclosed in claim 10, for example, Figures 1A-8E, do not show a closed ring shaped member must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-16, 18 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabbay US Patent 6,869,444 B2.

Gabbay discloses a heart valve prosthesis comprising a surgical implant (150), a curved member (176, 203, etc.) and a skirt (164, 174, 168, or 212, etc.).

Regarding claim 2, see col. 7, lines 1-10.

Regarding claim 3, the curved member can be called to element structure 203.

Regarding claim 4, see Fig. 14, showing wires coming out of element 432 (see wires before going up).

Regarding claim 6, see inner perimeter, in Fig. 15 (edge of section 468); then see struts (wires) 438 below edge of section 468.

Regarding claim 7, wires can be called prosthetic tissue.

Regarding claim 9, mesh 442 can be called fibrous mesh.

Regarding claim 10, see Figs. 1-4, 7-10 and 16-20.

Regarding claim 22, the Examiner believes that all the structure limitations can read on that claim. The word "mounted" has been interpreted broadly. In the Merriam-Webster Dictionary the word "mount" means the following: --- to arrange or assemble for use---. For the above reasons the spikes are mounted on the delivery apparatus because they are touching the walls of the delivery device.

Claims 19-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson, IV et al US Patent 6,042,607.

Williamson, IV et al discloses a heart valve delivery system comprising a delivery device comprising a plurality of tubes pairs (see Figs. 31-34E, elements 688 & 686), a plurality of self-closing clips (730), each clip having an open config. (see Fig. 34B) and a closed config. (see Fig. 34E), a first and second piercing ends (726). A first portion of the clip (722) slidably positioned in one tube and a second portion (724) slidably positioned in the other tube.

Regarding claim 20, see plunger in Fig. 32 element 704.

Regarding the prosthetic valve leaflet and the member supporting the leaflet in claim 22 see Fig. 2.

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Regarding claims 22-25 and 27-32, see Figs. 1-16.

Regarding claims 22 and 26-32, see Figs. 31-39D.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay US Patent 6,869,444 B2.

Gabbay discloses the invention substantially as claimed. However, Gabbay does not disclose a skirt made of ePTFE.

Gabbay teaches a skirt made of metal, plastic, synthetic materials, etc.. for the purpose of having a biocompatible implant.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the Gabbay reference in order to have a biocompatible material into the blood vessel.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3738

July 20, 2006.